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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

May 24, 1999

Subject: Docket No. 99D-0484, Draft Guidance for Industry on Accelerated Approval Products: Submission of Promotional Materials

Dear Sir/Madam,

Thank you for the opportunity to comment on the draft guidance. We have two specific concerns about the document which we have outlined below for your consideration.

The first concern is in regard to the timing of the submission of promotional material to FDA. The draft guidance appears to prohibit the submission of new promotional material in the first 90 days post-approval. And although it permits submission after the 90 day period, the sponsor would not be able to use the new materials until the 120 day post-approval period expired, even if FDA had no objection to their content. We believe that this is an unnecessary restriction unsupported by statute or FDA's other policies. This time period is an extremely critical one in launching a new product, and it is not always possible to foresee, prior to the launch of the product, the best mechanism for distributing information. It is especially important to allow for this evolution with products which represent new technologies and treatment options where rapid availability of information is critical. We suggest that the guidance be modified to allow for the submission of promotional material to FDA, and the dissemination of approved material, at any point in the post-approval period of the product.

The second point we would like to comment upon is the requirement for pre-release review of promotional materials for accelerated approval products until the Phase IV studies are completed and reviewed by FDA. We believe that this requirement places a substantial burden on the resources of industry as well as FDA. In some cases this requirement can extend many years into the post-approval period for a product when the boundaries for promotional claims have been thoroughly discussed and outlined. We support the Pharmaceutical Manufacturers Association comments regarding the draft Fast Track guidance that, as an alternative, FDA require pre-release review of promotional

99D-0484

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materials for accelerated approval products only until the sponsor demonstrates an understanding of FDA's promotional requirements for the products. Six months would seem to be adequate for such an understanding to be established.

We appreciate this opportunity to comment on the draft guidance document. Please contact me at (617)761-8990 if you have questions regarding this letter.

Sincerely,

Kathleen S. Grim

Kathleen S. Grim
Manager
Regulatory Affairs